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| APPLICATION NO.                     | I                  | FILING DATE  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|-------------------------------------|--------------------|--------------|----------------------|-------------------------|------------------|--|
| 10/829,544                          | 829,544 04/22/2004 |              | Adam J. Almen        | 2010.3-US-01            | 7295             |  |
| 22865                               | 7590               | 04/28/2006   |                      | EXAMINER                |                  |  |
|                                     |                    | ROUP, LLC    | PATEL, NATASHA       |                         |                  |  |
| 6500 CITY WEST PARKWAY<br>SUITE 100 |                    |              |                      | ART UNIT                | PAPER NUMBER     |  |
| MINNEAPO                            | OLIS, M            | N 55344-7704 | 3766                 |                         |                  |  |
|                                     |                    |              |                      | DATE MAILED: 04/28/2006 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   | Application No. Applicant(s) |   |                        |              |  |  |  |  |  |
|---|---|------------------------------|---|------------------------|--------------|--|--|--|--|--|
|   |   | 10/829,544                   |   | ALMEN, ADAM J.         |              |  |  |  |  |  |
|   | Office Action Summary   | Examiner                     |   | Art Unit               |              |  |  |  |  |  |
|   |   | Natasha N. Pate              | 1   | 3766                   |              |  |  |  |  |  |
| Period fo   | The MAILING DATE of this communication app<br>or Reply  | ears on the cove             | r sheet with the co                           | orrespondence ad       | dress        |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                              |   |                        |              |  |  |  |  |  |
| Status  |   |                              |   |                        |              |  |  |  |  |  |
| 1)[X]   | Responsive to communication(s) filed on 22 Ap   | oril 2004.                   |   |                        |              |  |  |  |  |  |
| •   |   | action is non-fin            | al.   |                        |              |  |  |  |  |  |
| 3)  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |                              |   |                        |              |  |  |  |  |  |
| ٠,۵   | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |                              |   |                        |              |  |  |  |  |  |
| Disposit  | ion of Claims   | •                            |   |                        |              |  |  |  |  |  |
| -   |   |                              |   |                        |              |  |  |  |  |  |
| <del>4</del> )🖂   | <ul> <li>4) ☐ Claim(s) 1-52 is/are pending in the application.</li> <li>4a) Of the above claim(s) 28-52 is/are withdrawn from consideration.</li> </ul> |                              |   |                        |              |  |  |  |  |  |
| 5)  | 5) Claim(s) is/are allowed.   |                              |   |                        |              |  |  |  |  |  |
| -   | 5)  |                              |   |                        |              |  |  |  |  |  |
| 7)  |   |                              |   |                        |              |  |  |  |  |  |
| ′=  | Claim(s) are subject to restriction and/or  | r election require           | ement.  |                        |              |  |  |  |  |  |
| Applicat  | ion Papers  |                              |   |                        |              |  |  |  |  |  |
|   | ·   | r                            |   |                        |              |  |  |  |  |  |
| 9)⊠ The specification is objected to by the Examiner.  10)⊠ The drawing(s) filed on <u>22 April 2004</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.   |   |                              |   |                        |              |  |  |  |  |  |
| יבשולפיו  | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                              |   |                        |              |  |  |  |  |  |
|   | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.05(a).                                 |                              |   |                        |              |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |                              |   |                        |              |  |  |  |  |  |
| ,—  | under 35 U.S.C. § 119   |                              |   |                        |              |  |  |  |  |  |
| -   | Acknowledgment is made of a claim for foreign   | priority under 3             | 5119 C & 110(a).                              | -(d) or (f)            |              |  |  |  |  |  |
|   | ☐ All b)☐ Some * c)☐ None of:   | phonty under 50              | 7 0.0.0. § 119(a)-                            | -(a) or (i).           |              |  |  |  |  |  |
| a)  | •   | s have been rec              | eived   |                        |              |  |  |  |  |  |
|   |   |                              |   |                        |              |  |  |  |  |  |
| <ul> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li> </ul>   |   |                              |   |                        |              |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |   |                              |   |                        |              |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |   |                              |   |                        |              |  |  |  |  |  |
| Coo the attached detailed office detail for a list of the contined copies not received.   |   |                              |   |                        |              |  |  |  |  |  |
|   |   |                              |   |                        |              |  |  |  |  |  |
| Attachmer   | nt(s)   |                              |   |                        |              |  |  |  |  |  |
| _   | ce of References Cited (PTO-892)  | 4) 🗀                         | Interview Summary (                           |                        |              |  |  |  |  |  |
| 2) 🔲 Noti   | ce of Draftsperson's Patent Drawing Review (PTO-948)  | 5, -                         | Paper No(s)/Mail Dat<br>Notice of Informal Pa |                        | D-152)       |  |  |  |  |  |
|   | rmation Disclosure Statement(s) (PTQ-1449 or PTO/SB/08) er No(s)/Mail Date 23-April-2004, 9/21/04   | 5) <u> </u>                  | Other:  | atent Application (PTC | J-192j       |  |  |  |  |  |
| I.S. Patent and   | Trademark Office 9/27/04  |                              |   |                        | -t- 20060220 |  |  |  |  |  |

#### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election without traverse of Claims 1-27 in a telephonic interview with Jeffrey R. Stone dated 4/4/06 is acknowledged.

Claims 28-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method of using the apparatus, there being no allowable generic or linking claim.

## **Drawings**

- 1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: element 35 in the detailed description for Figure 9.
- 2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: element 70 in Figure 6.
- 3. There are several other instances throughout the drawings of the application where the numbers do not match up with the detailed description. Appropriate correction is suggested.
- 4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the proper sequence of steps as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the

application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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## Claim Objections

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6. Claim 26 is objected to because of the following informalities: 'A heart rate variable signal processor' should actually read 'a heart rate variability signal processor'. Furthermore, 'the processor further capable' should read 'the heart rate variability signal processor further capable.' Appropriate correction is required.

7. Claims 24 and 25 are objected to because of the following informalities: 'receiving wireless transmission of the from the monitor' should read 'receiving wireless transmission from the monitor.' Also, 'receiving electronic transmission of wake or sleep signal from the monitor' should read "receiving electronic transmission of wake or sleep signal from the monitor.' Appropriate correction is required.

## Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 1-17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak et al. (US Patent 5,928,133) in view of Amano et al. (US Patent 6,126,595).
- 10. Regarding Claim 1, Halyak discloses a heart rate variability monitor (apparatus 10), comprising: at least two electrical contacts for detecting analog electrical signals generated within a body when placed in contact with the body (see sensor 12); a heart rate variability signal processor that monitors and analyzes the digital signal data and obtains heart rate variability data therefrom (see microprocessor 20); and a memory

capable of storing real time digital signal data (see col. 4, lines 17-20). The examiner considers that apparatus 10 is a heart rate variability monitor because it monitors (see Claim 1, first part) physiological properties such as heart rate (see col. 3, line 65) and changes in heart rate (see Claim 3, part 3). Although Halyak does not teach that the monitor is wrist-worn, he does disclose that the top and bottom of the wrist have been used for physiological tests with success (see col. 4, lines 58-59). Furthermore, Halyak does not disclose a circuit that conditions the electrical signals and converts the analog electrical signals to digital signal data. However, it is common and well known to include this signal-processing feature in physiological monitors. Amano teaches the conversion of analog signals to digital data (see A/D converter 444) in a similar wrist-worn monitor. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to digitize the data collected by the sensors for clearer signals that are easier to store. Finally, although Halyak does not disclose that the memory can hold at least 24 hours of the digital signal data, it would have been obvious to one of ordinary skill in the art at the time of the invention to use any period of time that would allow the storage of the most pertinent fluctuations in heart rate. Amano teaches that a one-day period would suffice in portraying these fluctuations (see col. 14, lines 39-45). Since Halyak discusses monitoring sleep, which occurs usually once a day for about 8 hours, using a 24-hour memory for storing heart rate variability data would have been an obvious choice by anyone looking to observe compare the different stages of sleep and the hours spent awake.

- 11. Regarding Claim 2, Halyak discloses the measurement of heart rate (see col. 3, lines 63-67). Halyak does not disclose that the electrical signals are ECG signals from the heart. However, the electrodes in the sensor are capable of picking up ECG signals from the heart when placed at the wrist as suggested. Thus, the examiner considers that ECG signals are a common parameter monitored by sleep researchers and would likely be used in Halyak's monitor.
- 12. Regarding Claim 3, Halyak discloses a processor that is capable of performing a heart rate variability test (see col. 4, lines 17-20). The examiner considers the microprocessor's ability to compare changing values equivalent to a variability test since changing values or fluctuations indicate a variability of the signal. If these values represent heart rate, then the microprocessor is essentially performing a heart rate variability test.
- 13. Regarding Claims 4, 5, and 6, Halyak discloses a processor that is capable of performing a heart rate variability test while a user sleeps (see block 52, Figure 4). Although Halyak does not explicitly disclose that his microprocessor performs a heart rate variability test while the user is awake and resting or while the user is physically active, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Halyak's microprocessor is capable of performing the intended use because it can be programmed to monitor heart rate variability (HRV) under each of those circumstances (sleep, rest, physical activity). Thus, Halyak's invention meets the claim.

- 14. Regarding Claim 7, Halyak discloses a processor that is capable of analyzing the heart rate variability to determine when the user is asleep (see line 32, Figure 3) and then performs a heart rate variability test during the sleep period (see block 52, Figure 4). The examiner considers that the threshold between consciousness and sleep can be used to determine when the user is asleep because falling below the threshold would mean the user has fallen asleep.
- 15. Regarding Claim 8, Halyak discloses a timer (see clock 18), wherein the timer is capable of timing the duration of the monitoring of the heart rate variability data (see col. 4, lines 15-17). The timer helps the microprocessor write the HRV data to memory at specified time intervals (see col. 4, lines 19-20). Thus, the timer is timing when to start and stop the monitoring—in other words the duration of the monitoring. Although Halyak does not explicitly disclose time-stamping the data, the examiner considers that clock 18 automatically time-stamps the data being that the data would be useless to the user if it did not contain information about when each sleep stage occurred and how long they lasted (see col. 4, lines 25-28). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to time-stamp the HRV data so that it can be analyzed afterwards.
- 16. Regarding Claim 9, Halyak discloses that the timer is capable of timing the duration of the heart rate variability test (see col. 4, lines 17-20). Since the heart rate variability test is performed during specified time intervals determined by the timer (clock 18), the duration is already timed and known.

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17. Regarding Claim 10, Halyak discloses a waking prompt (buzzer 22, Figure 2) capable of activation when a specified time for monitoring the heart rate variability has passed (see col. 3, lines 8-11). Halyak does not explicitly disclose that the processor stops monitoring heart rate variability when the waking prompt is activated. At the time the invention was made, it would have been an obvious to a person of ordinary skill in the art to stop microprocessor 20 from monitoring HRV in order to ensure that monitored data is taken at relevant times.

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- 18. Regarding Claim 11, Halyak discloses that the processor differentiates between a user's awake and sleep stages based upon heart rate variability data (see col. 4, lines 30-31). The examiner considers the user's awake stage is characterized by consciousness and the sleep stages are characterized by sleep and the ability of the processor to differentiate between the two is shown by producing Line 32 on the display or printer.
- 19. Regarding Claim 12, Halyak discloses that the processor differentiates between a user's awake state and non-REM sleep state based upon heart rate variability data (see col. 4, lines 30-38). The examiner considers non-REM to be the spikes that occur at the beginning and end of the REM cycle because the applicant discloses that non-REM occurs between the awake stage and the REM stage (see pg. 3, line2-5).
- 20. Regarding Claim 13, Halyak discloses that the waking prompt is activated when non-REM sleep state is recognized (see 45-54).

- 21. Regarding Claim 14, Halyak discloses that the processor recognizes differentiation between a non-REM sleep state (spikes 38) and a REM sleep state (36) based upon heart rate variability data (see col. 4, lines 30-35).
- 22. Regarding Claim 15, Halyak discloses a waking prompt, but does not explicitly disclose that the waking prompt is activated when REM sleep is recognized. However, it would be obvious to one of ordinary skill in the art at the time of the invention, to activate the prompt at some point in the sleep cycle because the applicant has not disclosed an apparent advantage of waking the user up at the immediate start of REM over waking the user up some time before REM, during non-REM. Waking someone up during non-REM sleep is going to give similar results to waking someone up just as soon as REM is detected. If the applicant were merely trying to prevent grogginess, then waking up a patient during non-REM would do the same thing. In essence, activating the waking prompt when REM is recognized is an obvious choice by anyone looking to prevent grogginess.
- 23. Regarding Claim 16, Halyak discloses a processor that is capable of performing a heart rate variability test during the non-REM sleep state even though for his purposes, Halyak chooses not to continue testing once the non-REM sleep state is detected (see col. 5, lines 24-29). However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since, Halyak's processor can be programmed to continue testing throughout the non-REM sleep state, Halyak's invention meets the claim. Similarly, the processor can

be programmed to stop the test when the REM sleep state is recognized since it is capable of differentiating between non-REM and REM sleep states.

- 24. Regarding Claim 17, Halyak discloses a processor that is capable of discerning and counting REM sleep state cycles and wherein the waking prompt is activated after a specified number of REM sleep state cycles are completed by a user (see col. 3, lines 27-33).
- 25. Further Regarding Claim 26, although Halyak does not teach that the monitor is wrist-worn, he does disclose that the top and bottom of the wrist have been used for physiological tests with success (see col. 4, lines 58-59). Halyak does not disclose that the electrical signals are ECG signals from the heart. However, the electrodes in the sensor are capable of picking up ECG signals from the heart when placed at the wrist as suggested. Thus, the examiner considers that ECG signals are a common parameter monitored by sleep researchers and would likely be used in Halyak's monitor (see col. lines 63-67). Furthermore, Halyak does not disclose a circuit that conditions the electrical signals and converts the analog electrical signals to digital signal data. However, it is common and well known to include this signal-processing feature in physiological monitors. Amano teaches the conversion of analog signals to digital data (see A/D converter 444) in a similar wrist-worn monitor. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to digitize the data collected by the sensors for clearer signals that are easier to store. Finally, although Halyak does not disclose that the memory can hold at least 24 hours of the digital signal data, it would have been obvious to one of ordinary skill in the art at the time of the

invention to use any period of time that would allow the storage of the most pertinent fluctuations in heart rate. Amano teaches that a one-day period would suffice in portraying these fluctuations (see col. 14, lines 39-45). Since Halyak discusses monitoring sleep, which occurs usually once a day for about 8 hours, using a 24-hour memory for storing heart rate variability data would have been an obvious choice by anyone looking to observe compare the different stages of sleep and the hours spent awake. Halyak does not disclose that the waking prompt is activated when REM sleep is recognized. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since Halyak's waking prompt can simply be programmed to activate when REM sleep is recognized without any additional structure, Halyak's invention meets the claim.

- 26. Claims 18-19 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak et al. (US Patent 5,928,133) and Amano et al. (US Patent 6,126,595) as applied to Claims 1-17 above in view of Atlas et al. (US Patent 6,265,978).
- 27. Regarding Claim 18, Halyak discloses a processor capable of monitoring heart rate variability data during a user's sleep period (see block 52, Figure 4). However, Halyak does not disclose the detection of a sleep apnea event. Atlas discloses a similar wrist-worn monitor that can be used to identify sleep apnea (see col. 10, lines 1-3). Because Altas teaches that apnea detection would be particularly applicable in sleep monitoring, one of ordinary skill in the art at the time of the invention would have found it obvious to provide such a feature in Halyak's sleep monitor, which also seeks to provide

user's with information about their awakening points and sleep interruptions (see '133 col. 2, lines 64-68).

- 28. Regarding Claim 19, Halyak discloses a waking prompt, wherein the waking prompt is activated when physiological information is detected (see col. 3, lines 17-20). Halyak does not disclose that the physiological information may include the presence of apnea. Because Altas teaches that apnea detection would be particularly applicable in sleep monitoring (see col. 10, lines 1-3), one of ordinary skill in the art at the time of the invention would have found it obvious to incorporate a waking prompt in Halyak's sleep monitoring and awakening device especially since apnea would entail temporary wakefulness and according to Halyak, it would be optimal to prompt a person at an already wakeful time (see col. 4, lines 38-44).
- 29. Regarding Claim 27, Halyak discloses a heart rate variability monitor (apparatus 10), comprising: a memory capable of storing real time digital signal data (see col. 4, lines 17-20); and a heart rate variability signal processor that monitors and analyzes the digital signal data and obtains heart rate variability data therefrom (see microprocessor 20); the processor further capable of performing a heart rate variability test (see col. 4, lines 17-20). The examiner considers the microprocessor's ability to compare changing values equivalent to a variability test since changing values or fluctuations indicate a variability of the signal. If these values represent heart rate, then the microprocessor is essentially performing a heart rate variability test. Halyak also discloses a timer that is capable of timing the duration of the heart rate variability test (see col. 4, lines 17-20).

Since the heart rate variability test is performed during specified time intervals determined by the timer (clock 18), the duration is already timed and known.

30. Further Regarding Claim 27, Halyak does not teach that the monitor is wristworn, he does disclose that the top and bottom of the wrist have been used for physiological tests with success (see col. 4, lines 58-59). Halyak does not disclose the specific use of optical sensors for detecting ECG signals generated by the body's heart. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to use any type of sensor that can pick up ECG signals. The applicant does not disclose any criticality in the use of optical sensors over any other suitable sensing mechanism (see pg. 17, lines 9-10). Optical sensors are well known and commonly used in biomedical applications as taught by Righter (see col. 4, lines 16-21). Thus, using an optical sensor would have been an obvious design choice by anyone looking for alternative methods of detecting ECG that did not require for example, a conductive gel that is often required by regular electrode type sensors. Halyak does not disclose that the electrical signals are ECG signals from the heart. However, the electrodes in the sensor are capable of picking up ECG signals from the heart when placed at the wrist as suggested. Thus, the examiner considers that ECG signals are a common parameter monitored by sleep researchers and would likely be used in Halyak's monitor (see col. 3, lines 63-67). Furthermore, Halyak does not disclose a circuit that conditions the electrical signals and converts the analog electrical signals to digital signal data. However, it is common and well known to include this signal-processing feature in physiological monitors. Amano teaches the conversion of analog signals to digital data

(see A/D converter 444) in a similar wrist-worn monitor. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to digitize the data collected by the sensors for clearer signals that are easier to store. Although Halyak does not disclose that the memory can hold at least 24 hours of the digital signal data, it would have been obvious to one of ordinary skill in the art at the time of the invention to use any period of time that would allow the storage of the most pertinent fluctuations in heart rate. Amano teaches that a one-day period would suffice in portraying these fluctuations (see col. 14, lines 39-45). Since Halyak discusses monitoring sleep, which occurs usually once a day for about 8 hours, using a 24-hour memory for storing heart rate variability data would have been an obvious choice by anyone looking to observe compare the different stages of sleep and the hours spent awake. Halyak does not disclose the detection of a sleep apnea event based upon the HRV data. Atlas discloses a similar wrist-worn monitor that can be used to identify sleep apnea (see col. 10, lines 1-3). Because Altas teaches that apnea detection would be particularly applicable in sleep monitoring, one of ordinary skill in the art at the time of the invention would have found it obvious to provide such a feature in Halyak's sleep monitor, which also seeks to provide user's with information about their awakening points and sleep interruptions (see '133 col. 2, lines 64-68). Halyak does not disclose that the waking prompt is activated when a sleep apnea event is recognized. Atlas discloses a similar wrist-worn monitor that can be used to identify sleep apnea (see col. 10, lines 1-3). Because Altas teaches that apnea detection would be particularly applicable in sleep monitoring, one of ordinary skill in the art at the time of the invention would have found it obvious to

provide such a feature in Halyak's sleep monitor, which also seeks to provide user's with information about their awakening points and sleep interruptions (see '133 col. 2, lines 64-68). Additionally, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since Halyak's waking prompt can simply be programmed to activate when a sleep apnea event is recognized without any additional structure, Halyak's invention meets the claim.

- 31. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak et al. (US Patent 5,928,133) and Amano et al. (US Patent 6,126,595) as applied to Claims 1-17 above in view of Gomes et al. (US Patent 4,570,637).
- 32. Regarding Claims 20, 21, and 22, Amano discloses the monitor having a back surface (see col. 23, lines 59-65). Amano does not disclose a porous, conductive membrane disposed on the back surface of the monitor and having contact with the user's skin to increase the monitor's ability to pick up the ECG signals. Nor does Amano disclose a conductive gel being incorporated into the pores of the conductive membrane to increase the monitor's ability to pick up the ECG signals. However, it is well known and common to incorporate these elements on a monitor having a sensor-type device especially because they are readily used with electrodes, whose main function is picking up ECG signals. Gomes is cited for his use of an electrode having a porous, conductive membrane impregnated with a conductive gel to increase the conductivity of the electrode thereby making it easy to pick up signals (see col. 5, line 62- col. 6, line 7). Thus, it would have been obvious to one of ordinary skill in the art at the time of the

invention to apply the same materials used to enhance a single electrode to enhance the conductivity between Amano's monitor and the skin because the monitor relies on analyzing the ECG signals and the better the signals, the more accurate the analysis.

- 33. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak et al. (US Patent 5,928,133) and Amano et al. (US Patent 6,126,595) as applied to Claims 1-17 above in view of Lind et al. (US Patent 6,889,165).
- Regarding Claim 23, Halyak does not disclose using his heart rate monitor to 34. control appliances in a home. Lind discloses a wrist-worn smart sensor module that monitors heart rate and downloads the data to a remote computer (see col. 11, lines 40-55). Lind discloses home information paths from the wrist worn heart rate monitor to each room (see pico-mode controller 215, Figure 11); at least one home control unit receiver (see site node controller 230) connectable to the transmission paths, installed in selected rooms for transmitting and receiving information along the transmission paths. The examiner considers the home control unit receivers are capable of being in separate rooms even though it is not explicitly disclosed because the information paths use communications means that can handle remote information transmission. Lind also discloses a central home control unit (see central network node 235), connectable to the transmission paths, the at least one home control unit receiver and to appliances in the rooms (see col. 12, lines 33-40). The examiner considers that the transmission paths can be established between the central home control unit and the appliances in the rooms as long as the appliances are smart appliances and have compatible sensor modules with which they can transmit/receive data. Lind does not disclose that the wrist

worn heart rate variability monitor is capable of transmitting an awake signal or a sleep signal to the at least one home control unit receiver based upon heart rate variability data. Nor does Lind disclose that the control unit receives the awake or sleep signal transmitted by the at least one control unit receiver, wherein when an awake signal is transmitted to the appliances by the computer, the appliances are turned on and when a sleep signal is transmitted by the computer, the appliances are turned off. However, just as Lind teaches that the computer receiving the heart rate data can be programmed to dial 911 in case of an emergency, it would be obvious to one of ordinary skill in the art at the time of the invention to program the computer to turn the appliances on and off according to the type of signal received from the heart monitor (see col. 11, lines 49-55) especially because some of the benefits of the smart sensor modules are minimal energy usage, as taught by Lind (see col. 10, lines 47-49 and 55-59).

- 35. Regarding Claims 24 and 25, Lind discloses that the home information transmission pathways are capable of receiving wireless transmission or electronic transmission from the monitor, the pathways wirelessly transmitting the signal to the central home control unit and the pathways wirelessly transmitting (see col. 4, lines 46-48) or electronically transmitting (see internet links, col. 7, lines 43-47) the signal to the home appliances. Although Lind does not disclose that the signal is a wake or sleep signal, Lind does disclose that heart rate data is transferred as a signal and the heart rate data encompasses the wake or sleep signal.
- 36. Regarding Claim 26, Halyak discloses a heart rate variability monitor (apparatus 10), comprising: at least two electrical contacts placed in contact with the body (see

sensor 12); a memory capable of storing real time digital signal data (see col. 4, lines 17-20); and a heart rate variability signal processor that monitors and analyzes the digital signal data and obtains heart rate variability data therefrom (see microprocessor 20); the processor further capable of performing a heart rate variability test, the processor further capable of differentiating between a user's awake and sleep stages based upon heart rate variability data (see col. 4, lines 17-20). The examiner considers the microprocessor's ability to compare changing values equivalent to a variability test since changing values or fluctuations indicate a variability of the signal. If these values represent heart rate, then the microprocessor is essentially performing a heart rate variability test. Halyak further discloses that the processor differentiates between a user's awake and sleep stages based upon heart rate variability data (see col. 4, lines 30-31). The examiner considers the user's awake stage is characterized by consciousness and the sleep stages are characterized by sleep and the ability of the processor to differentiate between the two is shown by producing Line 32 on the display or printer. Halyak also discloses a timer that is capable of timing the duration of the heart rate variability test (see col. 4, lines 17-20). Since the heart rate variability test is performed during specified time intervals determined by the timer (clock 18), the duration is already timed and known.

#### Conclusion

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

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38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

39. Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

NNP 4/7/06 Robert E. Pezzuto

Supervisory Patent Examiner

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